Special 510 (k) – PATHFAST® CK-MB-II Calibrator 1

510(k) SUMMARY

September 4, 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: k130628.

CONTACT:

Judi Smith
Precision *for* Medicine
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on behalf of:
Mitsubishi Chemical Medience Corporation
2-8, Shibaura 4-chome, Minato-ku
Tokyo, 108-8559 Japan

NAME OF DEVICE:

Trade Name:	PATHFAST CK-MB-II Calibrator 1
Common/Classification Names:	Calibrator
Regulation Number:	862.1150
Product Code:	JIT
Class:	II

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PREDICATE DEVICE: PATHFAST CK-MB-II Calibrator 1 which is supplied with the PATHFAST CK-MB-II Test [k081360, 8/17/2008]

DEVICE DESCRIPTION:

INTENDED USE:

The PATHFAST® CK-MB-II Calibrators are for calibration of the PATHFAST® system when used for the quantitative determination of creatine kinase-MB in human heparinized or EDTA whole blood and plasma.

PRODUCT DESCRIPTION:

The PATHFAST CK-MB-II Calibrators are used for calibration of the PATHFAST CK-MB-II test performed on the PATHFAST instrument. PATHFAST CK-MB-II test is an in vitro diagnostic test for the quantitative

measurement of creatine kinase-MB in heparinized or EDTA whole blood and plasma.

Currently, PATHAST CK-MB-II Calibrators 1 and 2 are provided as lyophilized products of two vials each. Calibrator 1 consists of saline and a preservative, and Calibrator 2 consists of CK-MB in buffer. Four vials of calibrator diluent also are provided for reconstitution of the calibrators. The diluent consists of an aqueous solution with 0.05% sodium azide. This Special 510(k) is being submitted for a change to a liquid Calibrator 1 formulation and a new dropper bottle container. There are no changes to PATHFAST CK-MB-II Calibrator 2. As a result of elimination of the reconstitution step for PATHFAST CK-MB-II Calibrator 1, the number of bottles of Calibrator Diluent is being reduced from four bottles to two bottles.

SUBSTANTIAL EQUIVALENCE:

The PATHFAST CK-MB-II Calibrator 1 (liquid format) is substantially equivalent to the PATHFAST CK-MB-II Calibrator 1 (lyophilized format) (K081360) in intended use and design. The similarities and differences are listed below.

Substantial Equivalence Comparison Table

SIMILARITIES		
Item	**PATHFAST CK-MB-II Calibrator 1 Lyophilized (predicate device)**	**PATHFAST CK-MB-II Calibrator 1 Liquid (Modified)**
FDA Submission Number	k081360	k130628
Intended Use	The PATHFAST® CK-MB-II Calibrators are for calibration of the PATHFAST® system when used for the quantitative determination of creatine kinase-MB in human heparinized or EDTA whole blood and plasma.	No change
Fundamental Scientific Technology	CK-MB concentration = 0 ng/mL. Provides zero analyte level for user calibration curve.	No change
Value Assignment	Primary calibrator, master calibrator, stock solution, working calibrator	No change
Instructions	Dispense approximately 100 µL of CAL-1 and CAL-2 in sample	No change

	wells to load on PATHFAST.	

DIFFERENCES		
Item	**PATHFAST CK-MB-II Calibrator 1 Lyophilized (predicate device)**	**PATHFAST CK-MB-II Calibrator 1 Liquid (Modified)**
Formulation	Lyophilized MOPS pH7.2, lactose, and enzyme free human serum, DTT	Liquid saline solution with 0.05% sodium azide as preservative
Format	Lyophilized	Liquid
Calibrator 1 Container	Silicon-coated glass bottle with silicon rubber and plastic screw cap	Polypropylene droplet bottle with high density polyethylene nozzle and polypropylene screw cap
Calibrator Quantity	CAL-1 (1mL lyophilized× 2vials) CAL-2 (1mL lyophilized×2vials) Calibrator Diluent (1mL×4 bottles)	CAL-1 (2mL liquid×1bottle) CAL-2 (1mL lyophilized ×2vials) (no change) Calibrator Diluent (1mL×2 bottles)
Instructions	Reconstitute each vial of CAL-1 and CAL-2 with one bottle (1mL) of Calibrator Diluent.	Reconstitute CAL-2 with one bottle (1mL) of Calibrator Diluent.

As part of the company's Design Control system, the following validation/verifications studies were performed.

- Formulation: assay sensitivity, Limit of Blank, Limit of Detection, Limit of Quantitation, accuracy, method comparison, matrix comparison, and precision
- Format: real time stability
- Container: elution and evaporation

The results of the validation and verification testing demonstrate that the modified PATHFAST CK-MB-II Calibrator 1 met all pre-established acceptance criteria for the studies identified in the company's design control system Risk Analysis. Therefore, the modified PATHFAST CK-MB-II Calibrator 1 is substantially equivalent to the current 510(k)-cleared PATHFAST CK-MB-II Calibrator 1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 4, 2013

Mitsubishi Chemical Medience Corporation
c/o Ms. Judi Smith
2 Bethesda Metro Center, Suite 850
Bethesda, MD 20814

Re: K130628
Trade/Device Name: PATHFAST CK-MB-II CALIBRATORS
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: II
Product Code: JIT
Dated: September 04, 2013
Received: September 05, 2013

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K130628

Device Name: PATHFAST® CK-MB-II Calibrators

Indication For Use:

The PATHFAST® CK-MB-II Calibrators are for calibration of the PATHFAST® system when used for the quantitative determination of creatine kinase-MB in human heparinized or EDTA whole blood and plasma.

Prescription Use __X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices and Radiological Health (OIR)

Ruth A. Chesler -S

Division Sign-Off
Office of In Vitro Devices and Radiological Health

510(k) k130628